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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,174	07/22/2005	Gerard Remkes	2565/132	7919
26646 7590 08/31/2009 KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004				
EXAMINER				
CHRISTIAN, MARJORIE ELLEN				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
08/31/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/543,174

Applicant(s)

REMKES ET AL.

Examiner

MARJORIE CHRISTIAN

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

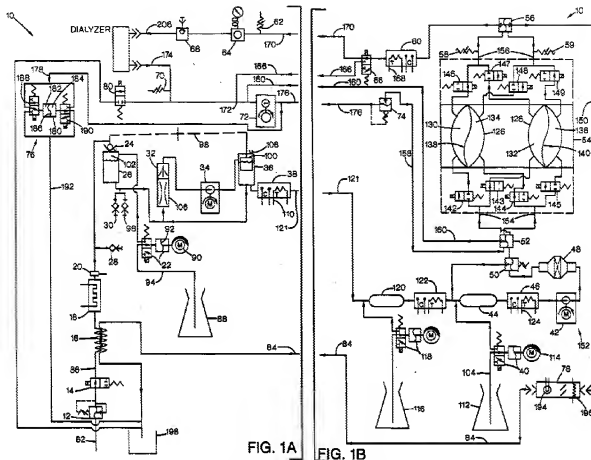
Response to Amendment

1. The amendment filed 4/17/2009 has been entered and fully considered.
2. **Claims 16-40** are pending. Support for amendments of **claims 16-40** are found in the specification as originally filed.

Claim Rejections - 35 USC § 102

3. **Claims 16-40 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,744,027, CONNELL et al. (hereinafter CONNELL).**

As to **Claim 16**, CONNELL discloses a method for supplying a dialyser with a dialysing fluid (Abstract), comprising: dialysing fluid concentrate in a receiving unit (Figs. 1A-B, Refs. 126, 128); water for diluting the dialysing fluid concentrate (82); mixing the dialysing fluid concentrate and the water in pre-set volumetric ratio (C16/L45-48); and setting a pre-set dialysing fluid flow rate over a pre-set treatment time (C16/L49-54 & C17/22-25), where the pre-set dialysing fluid flow rate is set at a value which depends upon the volume of the dialysing fluid concentrate at a commencement of treatment, volumetric ratio (C17/L1-15), and treatment time (C18/L18-20), at the end of the dialysis treatment the receiving unit is empty (C17/L33-44).



As to **Claim 17**, CONNELL discloses determining the flow rate before dialysis treatment from the volume of the dialysing fluid concentrate at the commencement of the dialysis treatment, volumetric ratio (C17/L1-15), and treatment time (C18/L18-20).

As to **Claim 18**, CONNELL discloses testing the dialysis unit before dialysis, comprising determining a volume of the dialysing fluid concentrate in the receiving unit before dialysis (C25/L51-55) from the volume of dialysing fluid concentrate at the commencement of the dialysis and dialysing fluid concentrate used during the time interval (C25/L64-C26/L6).

As to **Claims 19, 37**, CONNELL discloses a method for supplying a dialyser with a dialysing fluid (Abstract), comprising: dialysing fluid concentrate in a receiving unit (Figs. 1A-B, Refs. 126, 128); water for diluting the dialysing fluid concentrate (82); mixing the dialysing fluid concentrate and the water in pre-set volumetric ratio (C16/L45-48); and determining a dialysing fluid flow rate over a time interval of the dialysis treatment (C26/L19-36) where the dialysing fluid concentrate remaining in the receiving unit at the end of the dialysis treatment can be calculated from the volume of concentrate at the commencement of dialysis and amount of concentrate used during dialysis (C27/L21-61); and determining a dialysing fluid flow rate from a volume of the dialysing fluid concentrate in the receiving unit at the end dialysis, volumetric ratio (C17/L1-15), and remaining dialysis treatment time (C18/L18-20), wherein the dialysing fluid flow rate is the flow rate required for the remaining dialysis treatment time to ensure that at the end of dialysis the receiving unit is empty (C17/L33-44).

As to **Claim 20, 36**, CONNELL discloses at the end of treatment the receiving unit (126, 128) contains the residual volume of the dialysing fluid concentrate (88, 112), the method further comprising: discharging the pre-set residual volume of the dialysing fluid concentrate to waste (66, 166 & C21/L53-62, C6/L39-46).

As to **Claim 21**, CONNELL discloses diluting the residual volume of the dialysing fluid concentrate with water in a second volumetric ratio before the residual volume is discharged to waste (C7/L57-67), where dialysate removed from the recirculation loop is sent to the drain (198).

As to **Claim 22**, CONNELL discloses at the end of the pre-set treatment time the receiving unit is empty (C17/L33-37).

As to **Claim 23**, CONNELL discloses an apparatus for supplying a dialyser of a dialysis unit with a dialysing fluid (Abstract, Fig. 1A-B), comprising: receiving unit for dialysing fluid concentrate (Fig. 1B, Ref. 126, 128); *means for providing water* (82); *means for mixing* dialysing concentrate and water, the *means for mixing* is connected to the receiving unit and configured to receive dialysing fluid therefrom (C2/L58-65, 22, 40, 42, 12, 44, recirculation loop 158 and 52 thru 154); and a control and calculating unit (516) configured to set a dialysing fluid flow rate Q_d during a dialysis treatment, where at the end of the preset treatment the receiving unit is empty (C17/L33-44); wherein the dialysing fluid flow rate Q_d is dependent upon a pre-set volume of the fluid concentrate, pre-set volumetric ratio (C17/L1-15), and the treatment period (C18/L18-20).

As to **Claim 24**, CONNELL discloses the control and calculating unit (516) is designed such that a dialysing fluid flow rate Q_{db} is determined before dialysis from the pre-set volume of concentrate, pre-set volumetric ratio (C17/L1-15), and the treatment period (C18/L18-20), where it would naturally flow that the control and calculating unit adjusts dialysing fluid flow rate Q_{db} over the pre-set treatment period such that at the end of treatment the receiving unit contains a volume of fluid, absent evidence to the contrary.

As to **Claim 25**, CONNELL discloses the control and calculating unit (516) is configured such that a volume of concentrate in the receiving unit (126, 128) can be determined from the pre-set volume of concentrate at the commencement of treatment

and a volume of concentrate used during the pre-set time interval (C17/L22-47), where it naturally flows that the purpose is for a test of the apparatus (i.e. calibration).

As to **Claims 26, 40**, CONNELL discloses an apparatus for supplying a dialyser of a dialysis unit with a dialysing fluid (Abstract, Fig. 1A-B), comprising: receiving unit for dialysing fluid concentrate (Fig. 1B, Ref. 126, 128); *means for providing water* (82); *means for mixing* the dialysing concentrate and water, the *means for mixing* is connected to the receiving unit and configured to receive dialysing fluid therefrom (C2/L58-65, 22, 40, 42, 12, 44, recirculation loop 158 and 52 thru 154); the control and calculating unit (516) is configured to supply dialysing fluid to the dialyser and operates in association with the *means for mixing* (C2/L58-65, 22, 40, 42, 12), such that during a time interval of the dialysing treatment a fluid flow is set (C26/L19-36) such that dialysing fluid concentrate remains in the receiving unit at the end and can be determined from the volume of the dialysing fluid concentrate at the commencement and amount of the dialysing fluid concentrate used during dialysis (C27/L21-61), and at the end of treatment, a fluid flow rate is determined from a volume of concentrate in the receiving unit at the end of treatment, volumetric ratio (C17/L1-15), and remaining dialysis time (C18/L18-20), wherein the dialysing fluid flow rate is the flow rate required for the remaining dialysis treatment time to ensure that at the end of dialysis the receiving unit is empty (C17/L33-44).

As to **Claim 27**, CONNELL discloses *means for* discharging the pre-set residual volume of the dialysing fluid concentrate to waste via a waste discharge outlet (66, 166); at the end of the treatment period the receiving unit contains the pre-set residual volume

of the dialysing fluid concentrate (C17/L32-37), and the control and calculating unit (516) operates in association with the *means for* discharging (C21/L53-62). Where it naturally flows that at the end of the treatment period, the pre-set residual volume is *capable of* being discharged to the waste discharge outlet, absent evidence to the contrary.

As to **Claim 28**, CONNELL discloses *means for* mixing the pre-set residual volume of the dialysing fluid concentrate with water in a second pre-set volumetric ratio (C2/L58-65, 22, 40, 42, 12); wherein it naturally flows that the control and calculating unit (516) is configured such that the pre-set residual volume is *capable of* being diluted with water before the pre-set residual volume is discharged to the waste discharge outlet (66, 166).

As to **Claim 29**, CONNELL discloses at the end of the pre-set treatment period the receiving unit is empty (C17/L33-37).

As to **Claim 30**, CONNELL discloses *means for* inputting data relevant to the pre-set volume of dialysing fluid, volumetric ratio, and treatment period (Figs. 7-11).

As to **Claims 31-34**, CONNELL discloses that the fluid flow rate is preprogrammed and the controller the flow rates and pump speeds during dialyze mode (C17/L10-15). The manner of operating a device (i.e. maintaining or changing the fluid flow rate and treatment time) does not differentiate the apparatus for the prior art. As it has been held that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed

apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.

As to **Claim 35**, CONNELL discloses that there are two receiving units (126, 128).

As to **Claim 38**, CONNELL discloses testing the dialysis unit before dialysis, comprising determining a volume of the dialysing fluid concentrate in the receiving unit before dialysis (C25/L51-55) from the volume of dialysing fluid concentrate at the commencement of the dialysis and dialysing fluid concentrate used during the time interval (C25/L64-C26/L6).

As to **Claim 39**, CONNELL discloses *means for* discharging the pre-set residual volume of the dialysing fluid concentrate to waste via a waste discharge outlet (66, 166); at the end of the treatment period the receiving unit contains the pre-set residual volume of the dialysing fluid concentrate (C17/L32-37), and the control and calculating unit (516) operates in association with the *means for* discharging (C21/L53-62). Where it naturally flows that at the end of the treatment period, the pre-set residual volume *is capable of* being discharged to the waste discharge outlet, absent evidence to the contrary.

Response to Arguments

4. Applicant's arguments filed 4/17/2009 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the receiving unit contains only fluid concentrate) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additional arguments are not persuasive in light of the new grounds of rejection necessitated by amendment.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- US PGPub 2002/0023880, PEDRINI et al., as it discloses a method of purifying blood by controlling infusion rates of substitution fluids;
- WO98/50091, DROZ et al., as it discloses method and apparatus for controlling a dialysis device including substitution fluids; and
- US Patent No. 4,386,634, STASZ et al., as it discloses a proportioning system for dialysate fluid including use of concentrate and dilution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner, Art Unit 1797

MC